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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,349	11/17/2003	Ellen L. Berg	SEEK-001CON	7039

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EXAMINER
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ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/716,349	BERG ET AL.	
	Examiner	Art Unit	
	Karlheinz R. Skowronek	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-24* is/are pending in the application.

4a) Of the above claim(s) *18,23 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17 and 19-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 October 2007 has been entered.

Election/Restrictions

Applicant's election with traverse of the invention of claims 17 and 19-22 in the reply filed on 26 October 2007 is acknowledged. The traversal is on the ground(s) that both methods relate to a process wherein cells are contacted with an agent and changes are recorded to a biomap or a biological data set profile. This is not found persuasive because the methods have distinct steps the results of which distinguish a biomap from a biological data set profile. For example, claim 17 characterizes a biological data set profile that is limited to recorded measurements from test and control cell. The biomap of claim 23 is distinguished from the data set profile of claim 17 by requiring the recorded measurements to be further manipulated to produce normalized ratios from optimized parameter readouts. The method of claim 23 is further distinguished from the method of claim 17 via an additional analysis step using a multi-parameter pattern recognition algorithm. Thus claim 17, directed to method of

measuring and recording parameters in response to an agent is distinct from the method of claim 23, directed to a method of characterizing an agent by comparison of biomaps.

The requirement is still deemed proper and is therefore made FINAL.

Claim Status

Claims 17-24 are pending.

Claims 1-16 are cancelled.

Claim 24 is newly introduced.

Claims 18 and 23-24 stand withdrawn as being directed to a non-elected invention.

Claims 17 and 19-22 are being examined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

This rejection is reiterated from the previous office action.

Claim 17 and 19-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Friend et al. (US PAT 6,801,859), as evidenced by Cole et al. (US PAT 5,342,777).

Claim 17 is directed to a method of analyzing a candidate compound for a biological activity of interest, comprising contacting a test cell culture with said compound, wherein said culture comprises a plurality of factors in an amount sufficient to induce a plurality of pathways; measuring at least two parameters associated with said plurality of pathways and comparing the measurement of said at least two parameters with the measurement from a control cell culture lacking said compound, and recording said measurements of said test cell culture and said control cell culture to produce a biological dataset profile, wherein said biological dataset profile is indicative of the pathways that are active in said cell culture.

Friend et al teach a method of analyzing a candidate compound for a biological activity of interest, comprising contacting a test cell culture with said compound (col. 34, line 42-43); measuring at least two parameters associated with said plurality of pathways (col. 39, lines 32-33) and comparing (col. 39, lines 34-35) the measurement of said at least two parameters with the measurement from a control cell culture lacking said compound (col.39, line 31), and recording said measurements of said test cell culture and said control cell culture to produce a biological dataset profile (col. 16, lines 32-35), wherein said biological dataset profile is indicative of the pathways that are active in said cell culture. Friend et al teach the use of human kidney cells to evaluate drugs to generate consensus profiles (col. 10, line 56-59), reading on contacting cultured mammalian cells with a compound. Friend et al shows that to measure drug response data, cell are exposed to graded levels of the drug or drug candidate of interest (col. 34, line 42-43).

It is inherent to the culture of mammalian cells to include a plurality of factors that affect a plurality of signaling pathways as evidenced by Cole et al. who demonstrate the culturing of mammalian liver cells in a culture medium having growth promoting amounts of factors such as epidermal growth factor and retinoic acid among others (col. 3, line 13-26).

Regarding claim 19, Friend et al. teach cells derived from higher multi-cellular organisms (col. 6, lines 34-35) and cells derived from tissue (col. 44, line 66) reading on primary cells.

Regarding claim 20 and 21, Friend et al. teach the treatment of cells to increase or decrease in pathway activity (col. 52, line 19), which reads on treating with an inhibitor or activator of a pathway.

Regarding claim 22, Friend et al. teach the step of compiling a database of profiles (col. 24, lines 44-46).

Response to Arguments

Applicant's arguments filed 26 October 2007 have been fully considered but they are not persuasive. Applicant argues that Friend et al does not teach a method where an agent contacts a mammalian cell culture. In the passage from Friend (col. 10, line 56-59) highlighted in applicants remarks on p. 6, Friend et al indicates that human kidney cells are preferably tested to identify consensus profiles to evaluate drugs. Friend et al shows that to measure drug response data, cell are exposed to graded levels of the drug or drug candidate of interest (col. 34, line 42-43). In response to

applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the addition of factors simultaneously with the agent) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). With respect to applicant's arguments regarding claim 23, claim 23 was not rejected over Friend et al. In fact, Claim 23 was and remains withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or

would be obvious over, the reference claim(s). see, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Nonstatutory double patenting

Claims 17 and 19-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,656,695. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-16 of U.S. Patent No. 6,656,695 are species of claims 17 and 19-22 of the instant application.

Response to Arguments

Applicant has stated in the remarks at p. 11, filed 26 October 2007 that a terminal disclaimer was filed, however no disclaimer had been received with the amendment filed 26 October 2007. The double patenting rejection will be maintained until it is overcome with a terminal disclaimer.

Provisional nonstatutory double patenting

Claims 17 and 19-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 9, 10, 14, 33, 34, and 35 of copending Application No.10/220,999. Although the conflicting claims are not identical, they are not patentably distinct from each other because copending claims 1, 7, 9, 10, 14, 33, 34, and 35 are directed to identifying a mechanism of action of a biologically active agent on a cell in cell culture are species of claims 17 and 19-21

of the instant claims directed to the analysis of candidate compounds for biological activity of interest.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

The provisional double patenting rejection is being maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

16 January 2008

/KRS/
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